REMARKS

Claims 7, 9, 11, 13, 15, 17 and 21 were pending. Claim 7 is hereby canceled without prejudice. Claims 9, 11, 13 and 21 are amended. All claim amendments find support in the originally filed claims and the specification. Accordingly, no new matter is added by the amended claims. Claims 9, 11, 13, 15, 17 and 21 remain pending.

At the outset, Applicants wish to thank the Examiner, and her supervisor, for extending the courtesy of a telephonic interview yesterday with Applicants' attorney, Peter Shen. By this Reply, Applicants wish to address the Examiner's suggestions.

The Examiner indicates a potential objection to claims 7 and 21 as being substantially duplicative. Claim 7 has been canceled without prejudice to Applicants' right to pursue cancelled subject matter in other applications, thereby obviating any such objection.

Rejections Under 35 U.S.C. § 103(a)

Claims 7, 11, 13, 17 and 21 stand rejected as allegedly obvious under 35 U.S.C. § 103(a) over Di Bisceglie et al. ("Di Bisceglie") in view of either U.S. Patent No. 5,824,300 to Cummins or International Patent Publication No. WO 88/03411 to Cummins (collectively "Cummins"). Claims 9 and 15 are rejected in further view of Ratajczak. Withdrawal of the rejection of Claim 7 under 35 U.S.C. § 103(a) is respectfully requested in view of Applicants' cancellation of this claim without prejudice.

As discussed with the Examiner in yesterday's interview, Applicants assert that the combination of Di Bisceglie with Cummins is not proper for at least the following reasons. In a clinical study, Di Bisceglie used alpha-interferon therapy to treat hepatitis C virus (HCV) infection. Patients were subcutaneously injected with 6-7 million units per week which resulted in only about a 10% long-term success rate. Di Bisceglie references a pilot study reporting a 60% long-term success rate, and attributed the higher success to the use of higher doses of 2-5 million units per day. Di Bisceglie accordingly recommended even higher doses than those used in their study.

The NIH Consensus Statement of 1997 recommended 9 million units per week to treat HCV patients (document made of record in Applicants' June 18, 2002 Amendment). This recommendation by a respected panel of physicians further evidences that an ultra-high dose of alpha-interferon was the clinically accepted treatment for treating HCV with this drug.

Cummins teaches the use of low doses of alpha-interferon, but notably not for HCV (or even for any hepatitis). Instead, Cummins recommends low-dose alpha-interferon therapy to treat colds, cold sores, AIDS and warts.

It is well known that viral hepatitis is caused by at least five distinct viruses: hepatitis virus A, B, C, D and E. As noted in the literature, "[e]ach belongs to an entirely different family of viruses, and they have very little in common except the target organ they affect, the liver, and a certain degree of shared epidemiology." (Purcell, 1994, PNAS

91:2401-2406, first paragraph; copy attached hereto). Indeed, one of skill in the art would not expect therapies directed to hepatitis A, which is a DNA virus, to be efficacious for neutralizing hepatitis C, which is an RNA virus. "Moreover, the major genotypes [of HCV] differ from one another to the same degree that other RNA viruses belonging to separate subgenera differ." (Purcell at page 2403).

Given the differences among the hepatitis viruses themselves, the ordinarily skilled artisan would not believe that a treatment for HIV or the common cold would be of any help to an HCV patient. Moreover, Cummins discloses oral administration of the drug, which one of ordinary skill in the art would expect to be less effective (especially with respect to low doses) for HCV treatment than would direct injection.

In summary, one of ordinary skill in the art could not have been motivated, with any reasonable expectation of success, to practice the claimed invention which teaches using on the order of 0.1% of the recommended dose of alpha-interferon for the treatment of HCV, and even less motivated to administer this low dose orally.

Applicants have amended Claim 21 to replace the term "subject" for "human" as kindly suggested by the Examiner. The remaining claims have been amended as necessary to depend from Claim 21. Applicants respectfully assert that the claims, as amended, are in condition for allowance.

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Accordingly, Applicants respectfully submit that pending claims 9, 11, 13, 15, 17 and 21 are patentable over the cited art, and request withdrawal of the rejections of these claims under 35 U.S.C. § 103(a).

Conclusion

Applicants respectfully request reconsideration of the application, and entry of the foregoing remarks into the file history of the above-identified application. Applicants believe that in light of the foregoing amendments and remarks, the claims are in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding objections and rejections. An allowance is earnestly sought.

Respectfully submitted,

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Attachments